Tuesday, August 15







Preparing Early Adopter Countries for Maternal Vaccination: COVID-19, RSV, GBS

Maternal Immunization Readiness Initiative (MIRI) Demand Generation Formative Research Findings: Kenya Johns Hopkins Bloomberg School of Public Health



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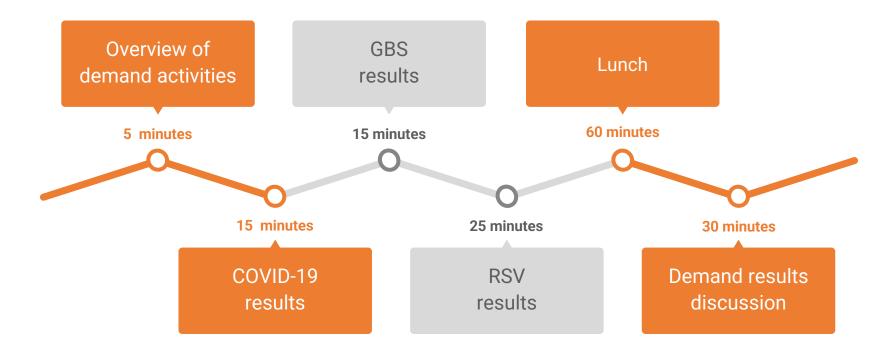
Clarice Lee, MSPH Student Research Assistant



Ruth Karron, MD MIRI Principal Investigator



Roadmap of demand activities: sessions for August 15









Overview of MIRI

Maternal Immunization Readiness Initiative (MIRI):

Conduct research to inform the future delivery of new maternal vaccines during pregnancy (COVID-19, RSV, GBS) in Kenya & Bangladesh

Immunization Readiness

Develop tools to assess readiness of MNH facilities for maternal immunization and quality of ANC before and after MI introduction

(Jhpiego)

Maternal Immunization Policy Assess the policy environment for maternal immunization COMIT: comitglobal.org

(Johns Hopkins Bloomberg School of Public Health)

Demand Generation & Communication

Gather insights on knowledge, attitudes, & behaviors, relevant to maternal immunization for demand generation strategies

(Johns Hopkins Bloomberg School of Public Health)







Objectives of demand generation and communication

Explore disease conceptualization of COVID-19, RSV, and GBS among pregnant and lactating women and other key stakeholders

2

Explore the decision-making process for maternal vaccines among pregnant and lactating women and other key stakeholders

3 Design communication strategies informed by research results and conduct rapid testing of such strategies









DAY ONE

- Examine the factors influencing the decisionmaking process for COVID-19 vaccines in pregnant and lactating people to inform demand generation strategies in Kenya and Bangladesh
- Examine the factors that could influence the decision-making process for **RSV and GBS** vaccines in pregnant and lactating people to inform demand generation strategies in Kenya and Bangladesh
- <u>Today: we will focus on results from Kenya only -</u> <u>COVID-19, RSV, GBS</u>







Results from Demand Generation Activities



- COVID-19 disease and vaccines
 - o Background
 - Findings from Kenya
 - Implications
- GBS disease and vaccines
 - o Background
 - o Findings from Kenya
 - Implications
- RSV disease and vaccines
 - o Background
 - Findings from Kenya
 - Implications







COVID-19 disease and vaccines

- Objective: Examine the factors that could influence the decision-making process for **COVID-19** vaccines in pregnant and lactating people to inform demand generation strategies
- Presenter: Prachi Singh

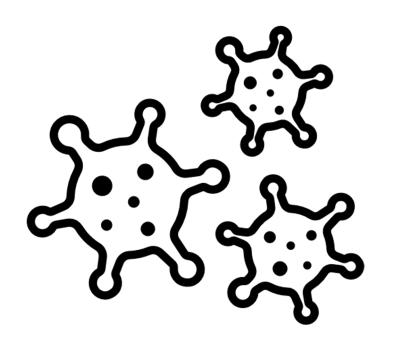








Background for COVID-19 Research



- COVID-19 vaccine trials have generally excluded pregnant women, despite their increased risk of severe COVID-19, including illness results in ICU admission, mechanical ventilation, and death compared to non-pregnant people
- Pregnant people with COVID-19 may also be at increased risk of adverse pregnancy outcomes compared to pregnant people without COVID-19



DAY ONE





Objective and Methods

<u>Objective</u>: Examine the factors that could influence the decision-making process for **COVID-19** vaccines in pregnant and lactating people

Study population:

- 1) Pregnant and lactating women (PLW)
- 2) Community members (CM)
- 3) Healthcare providers (HCP)
- 4) Policymakers (PM)

Qualitative methodology: In-depth interviews (IDIs)









Methods: Participants

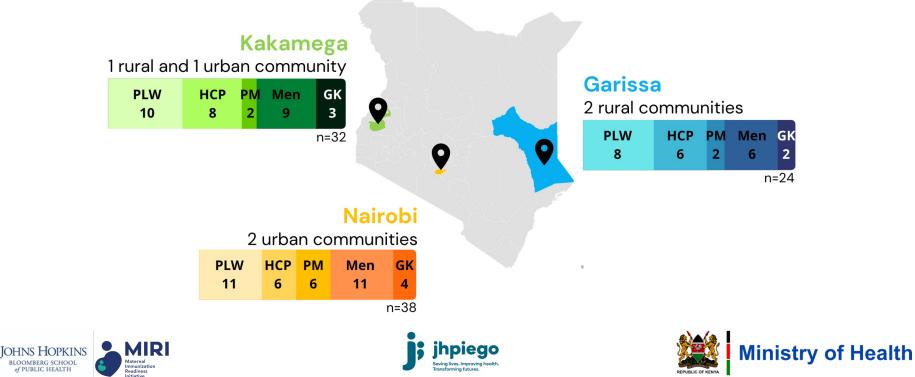
| Target Population Type | Rural | Urban | Total |
|--|-------|-------|-------|
| Pregnant & lactating women (PLW) | 14 | 15 | 29 |
| Family members & neighbors of PLW | 13 | 13 | 26 |
| Gatekeepers (religious leaders, community leaders) | 5 | 4 | 9 |
| HCPs (midwives, nurses, doctors, immunizers) | 10 | 10 | 20 |
| Policymakers (Kenya Midwifery Association, Kenya Paediatric Association, Kenya Obstetrician and Gynaecologist society, national vaccine and immunization program, maternal and neonatal health, deputy county directors of health) | 2 | 8 | 10 |
| | 44 | 50 | 94 |







Methods Study Population and Setting



Methods Data Analysis

- Conducted three rounds of open coding to finalize code list
- Coded transcripts and identified emerging themes
- Data were managed using Atlas.ti

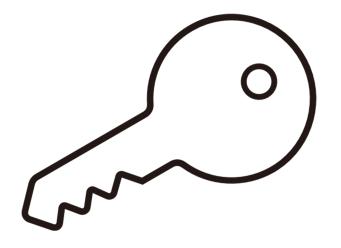








Results Key Themes



COVID-19 Vaccination Themes

- Individual: Safety, Myths, Risk Perception
- Interpersonal: Risk Perception, Norms, Religion
- Health Care System: Cost, Eligibility, Provider Recommendation
- Policy: Description, Implementation, Decision-making

Questions about Vaccines

Information Sources







COVID-19 Vaccination







Results Individual Level

Participants noted safety, myths circulating the COVID-19 vaccine, and perceived benefits of the vaccine as central factors for acceptance.

- Safety: "Some people were explaining about having some blood clot. That has also brought a lot of issues to the people, especially health workers and other people who are willing to take the vaccine." Healthcare provider, Garissa
- Myths: "Some say "I have just started giving birth and then they render me infertile and I don't even have one child." Someone else would be like "it's like the Chinese want to reduce Kenyans because Kenya has a huge debt." Male family member, Kakamega (urban)







Results Interpersonal Level: Peer Influence

Peer influences included both norms and religious influence.

• Norms: "I will consider being educated first and then seeing the number of people that will be vaccinated. If the mass of those who are afraid will be many, then I will be afraid too." Lactating mother, Kakamega (rural)

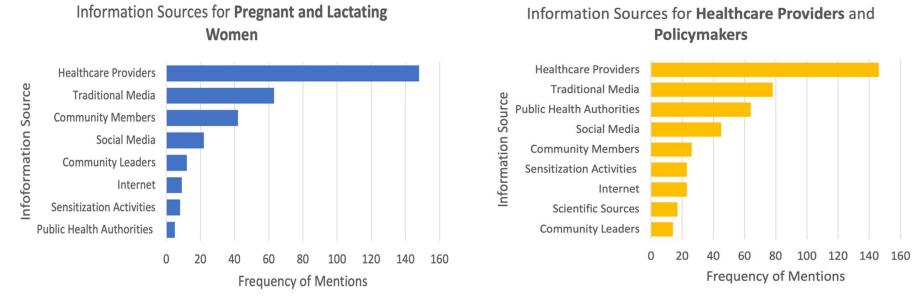


DAY ONE





Results Information Sources









Results Healthcare System Level

Participants noted cost, eligibility, and HCP recommendation as important factors within the healthcare system affecting vaccine acceptance.

- HCP Recommendation: "I just know pregnant women and breastfeeding women are contraindicated so I'm not even telling them to go for the vaccine." Healthcare provider, Kakamega (rural)
- Of the 20 healthcare workers interviewed, 8 would not recommend the COVID-19 vaccine to PLW or were hesitant about recommending the vaccine

*Note: data collection took place during the policy shift to include pregnant and lactating women in COVID-19 vaccination.







Results

Policy Level: Policy Guidance & Implementation

<u>Descriptions and implementation of COVID-19 vaccine policies:</u>

- Evident uncertainty around the national policy stance on the use of COVID-19 vaccines in PLW, including from health workers and policy makers.
- Policy for PLW ranged from unclear to exclusive to permissive

Decision making factors for vaccine policies include:

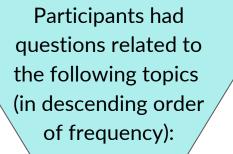
- Risk/burden of the disease
- Safety and effectiveness evidence for the vaccine
- Recommended by authoritative bodies







Results Questions about Vaccines



- Vaccine safety and administration
- Policy changes (i.e. changes in recommendations, eligibility)
- Benefits of vaccines
- Vaccine access
- COVID (i.e. questions about the disease, prevention, risk, etc.)
- Non-COVID-19 vaccines







Results: Summary of Findings in Kenya

INDIVIDUAL

- All have vaccine safety concerns: infertility, death, immobility
- COVID-19 risk perception is high

INTERPERSONAL

- Myths are ubiquitous; healthcare workers play a role in spreading myths
- PLW are highly influenced by their male family members
- Faith-based leaders hold the trust of their communities

HEALTH CARE SYSTEM LEVEL

- Healthcare provider recommendation is a critical influence
- Accessibility/cost are critical structural barriers

POLICY

- There is much uncertainty related to PLW recommendation
- Eligibility for PLW is unclear

QUESTIONS & INFORMATION SOURCES

- Safety, policy, and benefits of vaccines most frequent questions
- Healthcare providers are the most trusted source for vaccine info







Maps

Results

Presentation of Results

Presented at Vaccine Acceptance Research Network 2023 (won 1st place in Demand Generation track), Society of Behavioral Medicine 2023, Consortium of Universities of Global Health 2023







A socio-ecological comparison of the COVID-19 vaccine decisionmaking processes among pregnant and lactating women: Findings from Kenya and Bangladesh Prachi Singh BA¹, Berhaun Fesshaye MSPH¹, Eleonor Zavala MSPH¹, Clarice Lee MSPH¹, Ruth A. Karron MD³, Rupali J. Limaye MPH PhD¹

Background & Objectives Methods

Pregnant women are at increased risk for severe disease and poor health outcomes from COVID-19². Despite being mostly excluded from COVID-19 vaccine trails, real-world evidence suggests that Including i pregnant and lactating wome (PUW)² However, the second workers?

We conducted 233 lodgeth interviews with a variety of stakeholdera across without and traal settings in Kenga (= 84) and Bangladesh (= 44), including 51 PVV. 36 hashlarce workers, including nurses, mikehwise, doctors, and frontline workers; 36 community methes including family members of PVV; and 30 patkeespen including community and trabbased ladars. We applied a grounder theory approach to identify emerging themes.



vaccine decision-making process for this group is complex, as these persons are influenced by

numerous social, psychological, and structural

Graphs/Figures

factoret



At the individual level, women in our study overwhelmingly believed that the vaccines were able to prevent disease and the negative effects of COVID-19 for both mothers and babies. Concerns and myths related to vaccine safety were present in both countries, but the specific myths differed. At the interpersonal level, religio impacted attitudes and acceptability of the vaccine in both countries, and the entities with the greatest influence on PLW's vaccine decision-making were similar. At the healthcare system level for both countries, the recommendation of healthcare workers (HCW was crucial in informing PLW's decision-making process. However, HCWs exhibited confusion about PLW's eligibility in both countries, with some in Kenya hesitant to recommend the COVID vaccine for PLWs. At the policy level, vaccine nandates were important influences

Conclusions

This study demonstrates hav vaccine decision-making among PUW across global regions comprises both shared copering and using tradingens. Understanding these caperies and challenges is essential to inform immunization policy and demand generation activities for future vaccines. For communities. The results derived from this study can all to tailor communication efforts to increase vaccine acceptance and inform future maternal vaccine defivery strategies.



Acknowledgements

The Maternal Immunization Readiness Initiative (MIRI) project was funded by the Bill and Melinda Gates Foundation References

Allory J., Forandor S., Boret M., Stalling K., Tay, M., Ken Y. et al. Chickel manifestations, this factors, and material and producted oronomic masses 2013 in preguence, Their Intermetic Tevien and meta-analysis 807 2003; 2013 and 2014 (2014); preparation, Tevier and Chicken and Markan Structures. The Star St. Mayors TA, Maron PJ, Odrysto T, Panagotdakapotolos I, Marupet R, Oston CK, Liu R, Chang RT, Ellington SB.
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Vaccine

Publications: Kenya



Vaccine Volume 40, Issue 50, 28 November 2022, Pages 7305-7311

A socio-ecological exploration to identify factors influencing the COVID-19 vaccine decision-making process among pregnant and lactating women: Findings from Kenya

Rupali I. Limaye ^{a b c d 1} Q 🖾, Alicia Paul ^{b 2} 🖾, Rachel Gur-Arie ^{e 3} 🖾, Eleonor Zavala ^{a 4} 🖾, Clarice Lee ^{a 4} 🖂 , Berhaun Fesshave ^{a 4} 🖂 , Prachi Singh ^{b 5} 🖂 , Wincate Njagi ^{f 6} 🖂 , Paul Odila^{f6} 🖾 , Paul Munyao^{f6} 🖾 , Rosemary Njogu^{f6} 🖾 , Stephen Mutwiwa^{f6} 🖾 , Lisa Noguchi ^{g 7} 🖾 , Christopher Morgan ^{g 8} 🖾 , Ruth Karron ^{a 4} 🖾

Lack of clear national policy guidance on COVID-19 vaccines influences behaviors in pregnant and lactating women in Kenya

Eleonor Zavala 🤜 💿, Berhaun Fesshaye, Clarice Lee, Stephen Mutwiwa, Wincate Njagi, Paul Munyao, Rosemary Njogu, Rachel Gur-Arie, Alicia M. Paul, Taylor A. Holroyd, Prachi Singh, Ruth A. Karron & Rupali I. Limave 💌show less Article: 2127561 | Received 11 Aug 2022, Accepted 18 Sep 2022, Published online: 31 Oct 2022

Check for updates 66 Download citation 2 https://doi.org/10.1080/21645515.2022.2127561





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| | Conceptualizing the COVID-19 Pandemic: Perspectives of Pregnant and Lactating Women, Male Community Members, and Health Workers in Kenya | | | | | |
| | by 🕼 Alicia M. Paul 1.2.* 😒 💁 🚷 Clarice Lee 3, 🚷 Berhaun Fesshaye 3, 🚷 Rachel Gur-Arie ⁴ 🧕 🚷 Eleonor Zavala 3, 🚷 Prachi Singh 1 💁 🤬 Ruth A. Karron ⁵ and 🚷 Rupali J. Limaye 1.2.3.8.* 🖂 | | | | | |
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| | 6 Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD | | | | | |
| | 21205, USA • Authors to w Frontiers Frontiers in Communication Sections ~ Articles Research Topics | | | | | |
| | BRIEF RESEARCH REPORT article | | | | | |
| | Front. Commun., 25 January 2023 This article is part of the Research Topic | | | | | |

Sec. Health Communication Volume 8 - 2023 | https://doi.org/10.3389/fcomm.2023.995538

The Role of Media and Communications in Vaccine Hesitancy during the COVID-19 Pandemic

Editorial Board

A qualitative inquiry in understanding trusted media sources to reduce vaccine hesitancy among Kenyans

Berhaun Fesshaye^{1*}, Clarice Lee^{1,2*}, Alicia M. Paul^{1,2,3}, Eleonor Zavala¹, Prachi Singh², Ruth A. Karron^{1,4} and Rupali J. Limaye^{1,2,3,5*}

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Group B Streptococcus (GBS) disease and vaccines

- Objective: Examine the factors that could influence the decision-making process for GBS vaccines in pregnant and lactating people to inform demand generation strategies
- Presenter: Berhaun Fesshaye, MSPH









Methods: Study Design

Study population:

- 1) Pregnant and lactating women (PLW)
- 2) Community members (CM)
- 3) Healthcare providers (HCP)
- 4) Policymakers (PM)



Mixed method methodology:

- In-depth interviews (IDIs): Pregnant and lactating women, community members, healthcare providers, policymakers
- Cross-sectional surveys: healthcare providers







Methods Participants

Note: the sample was evenly split between urban and rural.

| | Target Population Type | Total |
|---------------------|--|-------|
| | Pregnant & lactating women | |
| | Community members | |
| Qualitative IDIs | HCPs (midwives, nurses, doctors, immunizers) | |
| | Policymakers | 10 |
| | | 50 |
| Quantitative | HCPs (midwives, nurses, doctors, immunizers) | |
| surveys | | 100 |







Methods Study Population and Setting



Survey: n=100 HCP total (50 in each county)







Methods Data Analysis

Quantitative Analysis

- Data were cleaned
- Preliminary data analysis was conducted
- Data were managed using Stata

Qualitative Analysis

- Conducted three rounds of open coding to finalize code list
- Coded transcripts and identified emerging themes
- Data were managed using Atlas.ti

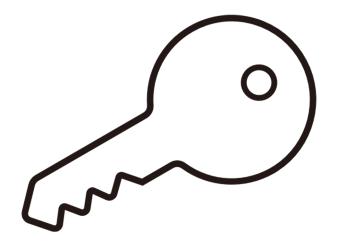








Results Key Themes



Qualitative (Pregnant and lactating women, community members, healthcare providers, policymakers) GBS Disease

- Awareness
- Knowledge
- Causes of adverse birth outcomes
- Testing and treatment

GBS Vaccines

- Vaccine acceptability
- Questions
- Vaccine decision-making influences

Quantitative (healthcare providers)

- Risk perception
- Vaccine confidence







GBS Disease



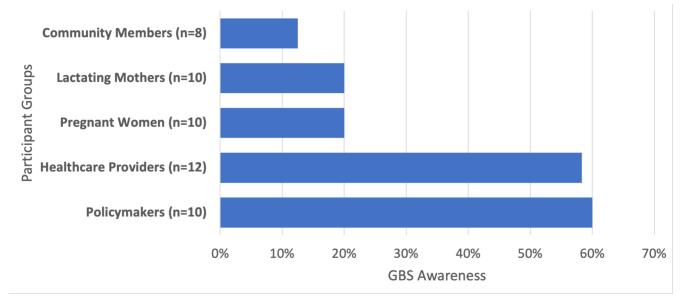




Results GBS Awareness

DAY ONE

• Participants were given a description of GBS and then asked if they had ever heard of it









Results GBS Knowledge

Most participants had not heard of GBS, especially pregnant women, lactating mothers, and community members.

• "We learned it in medical school but when we come here we forget about it or we test it if we have a premature rupture of membranes, we take a swab, I just do random testing not necessarily looking for the GBS. In terms of the medical practitioners themselves, that awareness, that reminder that this GBS is not in their head. We concentrate on the five big killers." Healthcare provider, Mombasa







Results Adverse Birth Outcomes

If participants were not aware of GBS, but described other outcomes, they were coded as "adverse birth outcomes"

These included stillbirth, neonatal infections, pneumonia, miscarriage, prematurity, etc.







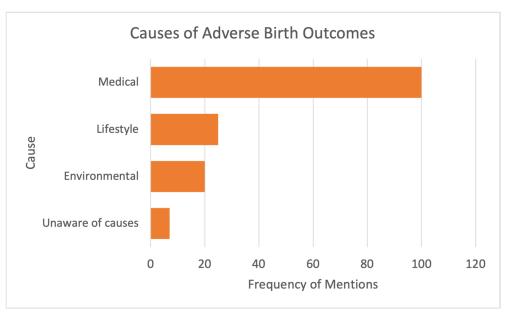
Results

Causes of Adverse Birth Outcomes

Participants were asked about causes of stillbirth and causes of illness in newborns. Responses were organized into the following categories:

- Medical (comorbidities, medicines)
- Lifestyle (working conditions, nutrition, rest during pregnancy)
- Environmental (cleanliness, temperature, etc.)
- Unaware of causes









Results GBS Testing & Treatment

- "Yes for now as I told you we have bigger problems, we have it on our list, probably when we start screening then we will know the burden." Healthcare provider, Mombasa
- "Since we are not able to actually diagnose it, we don't have a laboratory way of diagnosing it." Healthcare provider, Nakuru







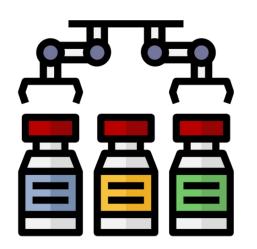
GBS Vaccines







Background GBS Vaccines



- A maternal GBS vaccine administered during pregnancy may prevent early and late-onset disease.
- A maternal vaccine may also mitigate the need for intrapartum antibiotic prophylaxis in otherwise healthy women.
- At least one GBS vaccine may be licensed and pre-qualified by 2026.







Results GBS Vaccine Acceptability

- "With time I need to trust it, and if it reaches majority of people it needs to work then I will be ok with it...If it comes tomorrow and I see people are getting it and they are ok and their children are ok, they are giving birth well, they have healthy babies, it has been there, I will go for it." Pregnant woman, Nakuru
- "Some people will say that vaccine is not good, it will cause babies to die so because of that there will be a lot of concerns about that new vaccine. I am ready because it may help us to give birth well and also our babies not to be infected with diseases." Lactating mother, Mombasa







Qualitative Results GBS Vaccine Questions

Participants had questions related to GBS vaccines (in descending order of frequency):

- 1. What are the side effects of the GBS vaccine?
- 2. What are the benefits of the GBS vaccine?
- 3. How does the GBS vaccine work, for the mother and baby?
- 4. Who will receive the GBS vaccine, and when?
- 5. How effective is the GBS vaccine?







Qualitative Results Vaccine Decision-making influences

Participants were asked who they believe should make the decision for a woman to receive a vaccine:

- 7/10 (70%) pregnant women report themselves as the primary vaccine decision-maker
- 8/10 (80%) lactating mothers reported themselves as the primary vaccine decision-maker







Qualitative Results Vaccine Decision-making influences

- "His life is his life. Mine is mine. If men got to see what women go through in the wards then they wouldn't oppose the woman's decision. Now that it's the woman who gets to witness it, the woman gets to decide. Nobody can influence that decision." Pregnant woman, Mombasa
 - "...so long as I have been told and understood it well, then I will just be jabbed." Lactating mother, Mombasa







Quantitative Results

- n=100 (50 from Nakuru, 50 from Mombasa)
- Sociodemographics: all healthcare providers
 - 87% from public facilities
 - o 67% were nurses
 - o 54% had at least one child







Quantitative Results GBS Risk Perception

| GBS disease risk perception: susceptibility and severity | Agree | Disagree | Don't Know |
|--|-------|----------|------------|
| The majority of pregnant women get GBS | 61% | 31% | 8% |
| GBS is dangerous for pregnant women | 87% | 12% | 1% |
| GBS is dangerous for fetuses and babies | 96% | 3% | 1% |







Quantitative Results Vaccine Confidence

| Maternal vaccine confidence | Agree | Disagree |
|--|-------|----------|
| I am confident that vaccine recommended for pregnant women during pregnancy are safe for pregnant women | 100% | 0% |
| I am confident that vaccine recommended for pregnant women during pregnancy are safe for fetuses and babies | 99% | 1% |







Quantitative Results Vaccine Recommendation

| Maternal vaccine recommendation | Likely | Unlikely |
|---|--------|------------------|
| If a new vaccine was approved for pregnant women and recommended by the Ministry of Health, how likely would you be to recommend the vaccine? | 97% | 3% |
| If a new vaccine was approved for pregnant women and recommended by the head doctor at your facility, how likely would you be to recommend the vaccine? | 89% | 11% |
| If a new vaccine was approved for pregnant women and the head doctor at your facility did not recommend it, how likely would you be to recommend the vaccine? | 53% | 47% |
| HNS HOPKINS BLOOMBERG SCHOOL BUOMBERG SCHOOL | | Ministry of Heal |

Respiratory Syncytial Virus (RSV) disease and vaccines

• Objective: Examine the factors that could influence the decision-making process for **RSV** vaccines in pregnant and lactating people to inform demand generation strategies



• Presenter: Rupali Limaye, PhD

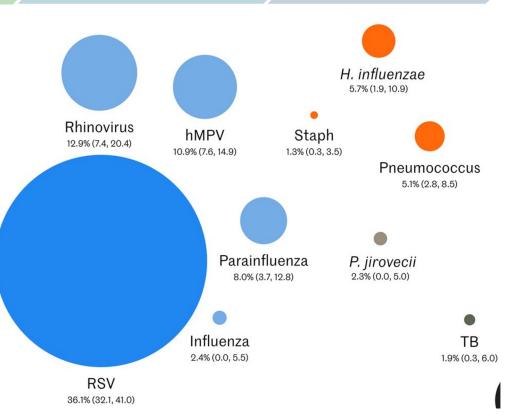






Background RSV in Kenya

RSV was the leading source of pneumonia requiring hospitalization in Kenya in a 2019 study



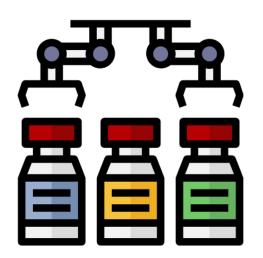
Source: Pneumonia Etiology Research for Child Health (PERCH) Study Group. Causes of severe pneumonia requiring hospital admission in children without HIV infection from Africa and Asia: the PERCH multi-country case-control study. Lancet. 2019 Aug 31;394(10200):757-779.







Background RSV Vaccines



- Multiple RSV vaccines are currently being developed: pregnant people are one target audience.
- At least one maternal RSV vaccine may be licensed and prequalified by 2024.







Methods Study Design

Study population:

- 1) Pregnant and lactating women (PLW)
- 2) Community members (CM)
- 3) Healthcare providers (HCP)
- 4) Policymakers (PM)



Mixed method methodology:

- In-depth interviews (IDIs): Pregnant and lactating women, community members, healthcare providers, policymakers
- Cross-sectional surveys: pregnant and lactating women







Methods Participants

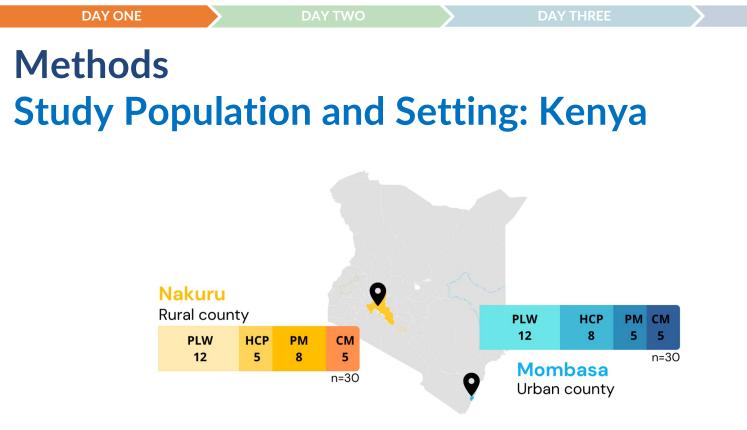
Note: the sample was evenly split between urban and rural.

| | Target Population Type | Total |
|----------------------|---|-------|
| Qualitative IDIs | Pregnant and lactating women (PLW) | 24 |
| | Community members (gatekeepers,relatives, male partners of PLW) | 10 |
| | HCPs (midwives, nurses, doctors, immunizers) | 16 |
| | Policymakers | 10 |
| Quantitative surveys | Pregnant and lactating women (PLW) | 400 |









Survey: n=400 PLW total (200 in each county)







Methods Data Analysis

Quantitative Analysis

- Data were cleaned
- Preliminary data analysis was conducted
- Data were managed using Stata

Qualitative Analysis

- Conducted three rounds of open coding to finalize code list
- Coded transcripts and identified emerging themes
- Data were managed using Atlas.ti









| DAY ONE | DAY IWO | | DAY THREE | | DAY FOUR |
|-----------------------|---------|--|-----------|--|---------------------------------------|
| Results Key Themes | RSV Dis | Term Knov | eness | | |
| |) : | ccination Indiv Decis Inter Healt HCP Polic Outro | n Themes | nfluence, Prioritiza on ngageme | tion, Eligibility, nt, Stakeholder |

Questions about Vaccines

Information Sources



DAVONE





RSV Disease







Qualitative Results Awareness of RSV

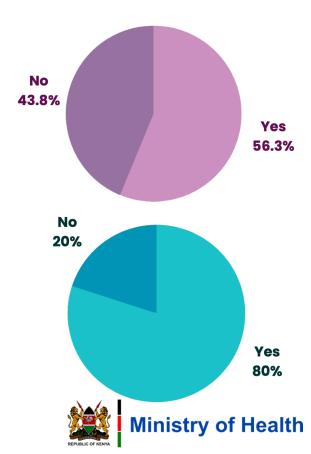
- Only 17 out of 60 participants had heard of the term "RSV" (28%)
 - All of them were healthcare providers (HCP) or policymakers (PM)

But when we showed participants a video of baby with <u>RSV wheezing</u> and asked if they had seen/heard it before

- 57 out of 60 participants said yes (95%)
- 1 PW, 1 LM, 1 CM said no; all from Nakuru (rural)





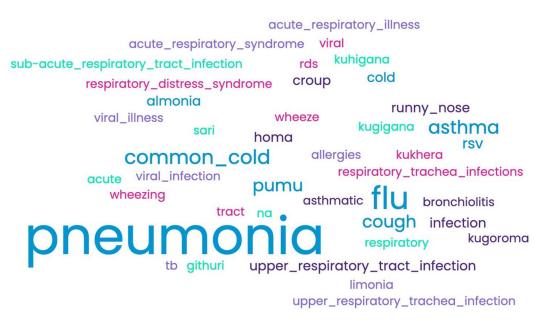


Qualitative Results: RSV Terms

More than 30 terms were used to describe RSV and/or RSV-associated wheezing

- Pneumonia (including acute and severe pneumonia) was the most mentioned across all target groups
- PLW and community members tended to use flu, common cold, asthma
- Terms containing "respiratory" (URTI, respiratory distress, respiratory illness) were used only by HCP and PM





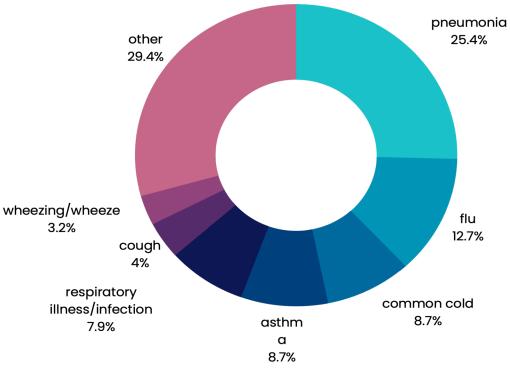




Ministry of Health

Qualitative Results: RSV Terms

- pneumonia (including acute and severe pneumonia) was the most mentioned across all target groups
- PLW and community members tended to use flu, common cold, asthma
- terms containing "respiratory" (i.e. URTI, respiratory distress, respiratory illness) were used only by HCP and PM







Qualitative Results RSV Knowledge: Causes

Although participants recognized RSV disease presentation, most were not aware it is caused by a virus.

- "These ones that get it are still children, and their immunity system is still low, it is not yet like for grown-ups. So they are prone to so much disease. I am a breastfeeding mum my child in one way or another can get the infection that am having. I breastfeed her, when I breathe maybe there are some clothes I might be using and maybe with bad luck she uses the same and gets affected." Community member, Mombasa
- "The child's mother exposed the child to cold water and the mother did not have him wear shoes or sock. So the cold got into this child." Lactating mother, Mombasa







Qualitative Results RSV Knowledge: Symptoms

• "The common thing is a cough, running nose and a wheeze - those are the most common - and sometimes fever." Healthcare provider, Mombasa (urban)

• "They are not able to cough as if there are mucus somewhere and also difficulty in breathing." Pregnant woman, Nakuru (rural)







Qualitative Results RSV Knowledge: Seasonality

• "Usually in cold seasons and rainy seasons." Lactating mother, Mombasa

• "Mostly towards the beginning of the hot season, probably. But it can be across the seasons." Healthcare provider, Mombasa







Qualitative Results RSV Knowledge: Conflation with other diseases

- "You know the main problem is difficulty in breathing. So you find people do not go to the hospital immediately because they usually think it is flu they do not know it is pneumonia. After that the baby may die or now you have the problem of looking for doctors." Community member, Mombasa
- "For my son even when very hot, especially when there was a lot of pollen, I remember pollen during windy times when it was very hot he would get an attack and also when it was very cold. So, I cannot really say it was seasonal, it would come any time." Pregnant woman, Mombasa







Qualitative Results RSV Knowledge: Community burden

- "It is a big problem because if a person falls sick and is not treated well, a person can die. Because the temperatures rise until it very high you know it is easy for a person to lose their life." Community member, Mombasa
- "It's quite common in children under two years." Healthcare provider, Mombasa
- "Yes, there is an outbreak of it in the community because almost everybody is having it." Lactating mother, Mombasa







Qualitative Results RSV Treatment

- "It can be separated but I don't think we have that parameter to single out each virus. If we see the signs of bacteria...we try to use an antibiotic to cover that spectrum. But if everything is within the normal parameters, vitals are fine, low grade fevers, no test showing that it is an acute bacteria or infection, then we manage symptomatically." Healthcare provider, Mombasa
- "We only explain to them that this is a viral illness and it is severe because even when we know it is RSV we manage symptoms - if there is fever we give antibiotics, if there is pain we give painkillers." Policymaker, Nakuru







RSV Vaccines







Socio-ecological model of vaccine decisionmaking

Policy level: Community engagement; stakeholder outreach and training; facility readiness

Healthcare system level: Healthcare provider recommendation; eligibility; prioritization

> Interpersonal level: Peer influence; religion

> > Individual level: Perceived benefits of vaccine; vaccine safety; decision-making influences







Qualitative Results Individual Level: Perceived Benefits

- "As I said, it might take a lot of convincing [to receive an RSV vaccine] because you see getting a disease that affects 1 in 10, I still don't think that is a reason for me to get the vaccine. We have to be 9 over 10 and know that this disease is really, really bad you know?" Pregnant woman, Mombasa
- "[An RSV vaccine] is good because it prevents when you give birth the baby will not have problems and even it they will get it it will not be that strong, it will be somehow not strong because already you have treated them when they are in the mothers' womb." Lactating mother, Nakuru







Qualitative Results Individual Level: Safety

"I support the vaccine, it's just how safe is it, so long as it is safe and does not cause any side-effects later, not to have later side-effects then it will be good, I advocate for prevention than cure, than medication itself, treatment"
 Community member, Mombasa







Qualitative Results Individual Level: Vaccine Decision-Making

Participants were asked who they believe should make the decision for a woman to receive a vaccine:

- **16/18 (89%) lactating mothers** reported themselves as a primary vaccine decision-maker
- 4/6 (67%) pregnant women reported themselves as a primary vaccine decision-maker







Qualitative Results Individual Level: Vaccine Decision-Making

- "There is no part I should involve parents or my family because this is my child and his life I am protecting it is I who should know, my child needs this. Yes, I may ask my mother and if she tells me no and then I do not take him, I am the one who will lose and will be hurting my baby. I should be the one who should decide." Lactating mother, Nakuru
- "If maybe [my husband] wants me to get the vaccine and then I follow whatever he has said, because I know he would want good things for me. Maybe I don't know much concerning that, about the vaccine and maybe he insists that it's good so I would not doubt him." Pregnant woman, Nakuru
- "The final decision is normally the doctor. I cannot say I do not want because they have already done the research and know it can help me." Pregnant woman, Nakuru







Ministry of Health

Qualitative Results Interpersonal Level: Peer influence

- "Also peer pressure, you know you do not want to risk, when you see many people are getting it, there is that fear as to why they are going for it. So definitely you would also want, so I might go for it." Lactating mother, Nakuru
- "Mostly men [will be hesitant]. They can still affect the other groups, they will influence them about the uptake, some of them they will discourage the other groups." Healthcare provider, Mombasa







Qualitative Results Interpersonal Level: Religion

- "[Religious leaders] have influence on how women take vaccines. In some part
 of that community, they only listen to one leader. If that leader tells them this
 thing is good, they follow them and it's their belief so you have to respect it."
 Healthcare provider, Mombasa
- "Most (religious leaders) ignore [vaccines] they do not see if it is important because they are putting God ahead: He is their priority. They will tell you vaccines are not important God so put God ahead of everything." Pregnant woman, Mombasa







Qualitative Results Healthcare System Level: Prioritization, Eligibility, & HCP Recommendation

- "Those who have low immunity starting with pregnant mothers, chronic illnesses, and the elderly should be prioritized." Healthcare provider, Mombasa
- "I don't have any concerns with vaccines. Obviously, the vaccine is developed after fully and thorough research. Everything has its side effects. Do the benefits outweigh the risks?" Healthcare provider, Mombasa







Qualitative Results Policy Level: Community Engagement

• "Definitely, you have to consult the recipients, before a new vaccine is introduced - the community members, sensitization of the community is key and critical. They should clearly understand the benefits of this vaccination and once they actually understand then it becomes easier for them to actually accept to be vaccinated." Policymaker, Mombasa







Qualitative Results Policy Level: Stakeholder Outreach & Training

• "We have worked with developing committees related to maternal child health and we know the people who challenge us most, it is not the women it is the men within the society and the chief stakeholders like religious leaders and civil society." Policymaker, Nakuru







Qualitative Results Policy Level: Facility Readiness

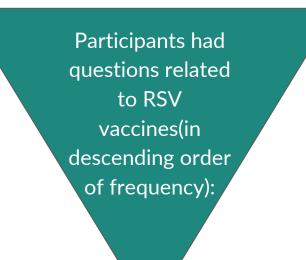
• "Yes, I will recommend if we have been trained and know the benefits of it. It must be communicated that it is not a trial or an experiment. So a sustainable program, availability, knowing the benefits of the vaccine, training of the healthcare workers on its safety, and then what tools do we need?" Healthcare provider, Mombasa







Qualitative Results Questions about RSV Vaccines



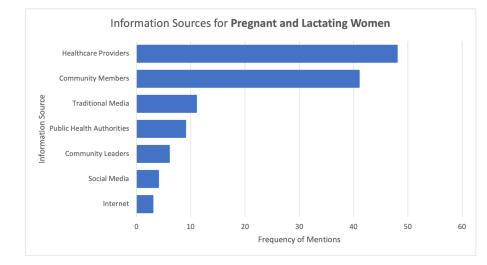
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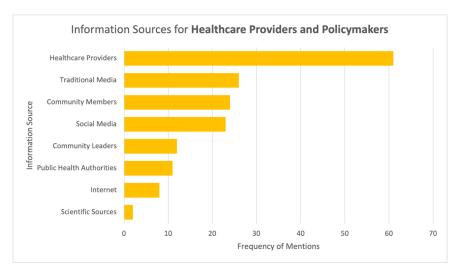
- 1. What will be the potential side effects/risks of the vaccine for the mother and/or baby?
- 2. How will the vaccine work to protect the baby if it is given to the mother? Why will the mother be given the vaccine and not the baby?
- 3. What will the vaccination schedule be (which trimester, how many doses)?
- 4. What will the benefits of the RSV vaccine be?
- 5. How effective will the RSV vaccine be? Will it prevent infection or reduce severity of the disease?





Qualitative Results Information Sources











Qualitative Results Negative Information Sources

Participants discussed sources they do not trust or those that spread misinformation.

- "They do get information from the neighbors and friends but when they come here we try to demystify because they are being told many things - don't take this vaccine when you are pregnant, the baby will come out sick." Healthcare provider, Mombasa
- "You know social media it has advantages and disadvantages. A wild rumor can spread like a bushfire, I think you know about the tetanus toxoid vaccine. So it has a major role to play but there are pros and cons." Policymaker, Mombasa







Quantitative Results: Characteristics of Study Participants (n=400)

- Approximately 1/3 (35%) of participants were pregnant with their first child (primagravida) or breastfeeding their first child
- Approximately 2/3 (65%) of participants were multigravida or breastfeeding a subsequent child
- Approximately 1/4 of participants inundated that they were pregnant
 - Among pregnant participants, 45% were in their second trimesters and 55% were in their third trimester







| DAY ONE | DAY TWO | | DAY THREE | | DAY F |
|---------|----------------------------------|-------------------------|---|--|-------|
| Fa | ctor | Total sample (n=400) | Primagravida or breastfeeding first child (n=140, 35.2%) | Multigravada or breastfeeding subsequent child (n=260, 64.8%) | |
| Ge | nder | | | | - |
| | Female | 400 (100%) | 140 (100%) | 260 (100%) | _ |
| Ag | e | | | | |
| | 18-29 | 269 (67.2%) | 130 (92.9%) | 139 (76.2%) | |
| | 30-44 | 131 (32.8%) | 10 (7.1%) | 121 (46.5%) | _ |
| Pre | egnancy status | | | | - |
| | Pregnant | 101 (25.2%) | 39 (27.9%) | 62 (23.8%) | |
| | Lactating / not pregnant | 299 (74.8%) | 101 (72.1%) | 198 (76.2%) | |
| Tri | mester (if pregnant) | | | | - |
| | Second trimester | 45 (44.6%) | 19 (49.0%) | 26 (42.9%) | |
| | Third trimester | 56 (55.4%) | 20 (51.0%) | 36 (58.0%) | |
| Ed | ucation level | | | | - |
| | Less than primary school | 45 (11.2%) | 1 (0.7%) | 44 (16.9%) | |
| | Primary school | 130 (32.5%) | 34 (24.3%) | 96 (36.9%) | |
| | Secondary/high school | 121 (30.2%) | 49 (35.0%) | 72 (27.7%) | |
| | College/university/post-graduate | 104 (26.0%) | 56 (40.0%) | 48 (18.5%) | |

*Primagravida or breastfeeding first child = Pregnant persons reporting no children (under age 18) and lactating persons reporting one child; Multigravida = pregnant persons reporting one or more child and lactating persons reporting two or more children









Quantitative Results: Items

| Construct | Item | Answer Options | | |
|--|---|-------------------------------|--|--|
| Perceived prevalence | The majority of babies <2 years old get RSV. | | | |
| Perceived risk: susceptibility of baby | I worry that my baby could get RSV. | Strongly Agree Agree | | |
| Perceived risk: severity for baby | I believe RSV is dangerous for babies. | Disagree Strongly Disagree | | |
| Perceived risk: severity for mother | I believe RSV is dangerous for pregnant women or women who have recently given birth. | Don't Know | | |
| Social norms: peer descriptive norm | If there was a Ministry of Health approved maternal vaccine for RSV, the majority of my pregnant friends and family would get it. | | | |
| Social norms: peer injunctive norm | If there was an approved maternal vaccine for RSV, the majority of my friends and family would encourage me to get it. | | | |
| Self-efficacy | I have some control over whether or not I get vaccines during my pregnancy. | | | |
| Perceived barriers | If I need to visit a health facility for an appointment or a vaccine, I can easily go to that health facility. | Strongly Agree Agree | | |
| Safety: baby | I am confident that vaccines recommended for me during pregnancy are safe for my baby. | Disagree Strongly | | |
| Safety: mother | I am confident that vaccines recommended for me during pregnancy are safe for me. | Disagree | | |
| Vaccine effectiveness: baby | If a new vaccine were approved for use among pregnant women, I trust that the vaccine would protect the fetus. | | | |
| Vaccine effectiveness: mother | If a new vaccine were approved for use among pregnant women, I trust that the vaccine would protect me | | | |







Ministry of Health

Quantitative Results: Knowledge, Attitudes, and Behaviors by Pregnancy Status

| Construct (<u>number</u> of items) | Level | Total (n=400) | Currently pregnant 101 (25.2%) | Not pregnant (currently lactating) [†] 300 (74.8%) | p-value |
|--|-------------------------------------|-------------------------|-----------------------------------|--|---------|
| Perceived prevalence | High perceived RSV prevalence | 347 (86.5%) | 84 (83.2%) | 263 (87.7%) | 0.25 |
| (1 item) | Low perceived RSV prevalence | 54 (13.5) | 17 (16.8) | 37 (12.3) | |
| Perceived risk | High perceived RSV risk | 215 (53.6) | 44 (43.6) | 171 (57.0) | 0.051 |
| (3 items) | Moderate perceived RSV risk | 155 (38.7) | 46 (45.5) | 109 (36.3) | |
| | Low perceived RSV risk | 31 (7.7) | 11 (10.9) | 20 (6.7) | |
| Social norms | High supportive norms | 319 (79.6) | 82 (81.2) | 237 (79.0) | 0.64 |
| (2 items) | Low supportive norms | 82 (20.4) | 19 (18.8) | 63 (21.0) | 1 l' |
| Self-efficacy | High self-efficacy | 347 (86.5) | 86 (85.1) | 261 (87.0) | 0.64 |
| (1 item) | Low self-efficacy | 54 (13.5) | 15 (14.9) | 39 (13.0) | |
| Perceived barriers | Low perceived barriers | 333 (83.0) | 86 (85.1) | 247 (82.3) | 0.51 |
| (1 item) | High perceived barriers | 68 (17.0) | 15 (14.9) | 53 (17.7) | 1 |
| Safety | High confidence in vaccine safety | 389 (97.0) | 98 (97.0) | 291 (97.0) | 0.99 |
| (2 items) | Low confidence in vaccine safety | 12 (3.0) | 3 (3.0) | 9 (3.0) | 1 |
| Vaccine effectiveness | High trust in vaccine effectiveness | 357 (89.0) | 86 (85.1) | 271 (90.3) | 0.15 |
| (2 items) | Low trust in vaccine effectiveness | 44 (11.0) | 15 (14.9) | 29 (9.7) |] |

Quantitative Results

Knowledge, attitudes, and beliefs of sample, stratified by number of children:

- Women were significantly more likely to have higher perceived prevalence of RSV if they were multigravida or breastfeeding a subsequent child.
- Women who were multigravida or breastfeeding a subsequent child had significantly higher perceived risk of RSV.



| | Construct (no. of items) | Level | Total (n=400) | Primagravida or breastfeeding first child (n=140, 35.2%) | Multigravada or breastfeeding subsequent child (n=260, 64.8%) | p- value | |
|--|---------------------------------------|------------------------------------|-------------------------|---|---|-------------|--|
| | Perceived | Higher perceived RSV prevalence | 346 (86.5% | 112 (80.0%) | 234 (90.0%) | 0.005 | |
| | prevalence <i>(1 item)</i> | Lower perceived RSV prevalence | 54 (13.5%) | 28 (20.0%) | 26 (10.0%) | 0.005 | |
| | Perceived risk <i>(3 items)</i> | Higher perceived RSV risk | 214 (53.5%) | 69 (49.3%) | 145 (55.8%) | | |
| | | Moderate perceived RSV risk | 155 (38.8%) | 54 (38.6%) | 101 (38.8%) | 0.048 | |
| | | Lower perceived RSV risk | 31 (7.8%) | 17 (12.1%) | 14 (5.4%) | | |
| | Social norms (2 items) | High supportive norms | 318 (79.5%) | 109 (77.9%) | 209 (80.4%) | 0.55 | |
| | | Low supportive norms | 82 (20.5%) | 31 (22.1%) | 51 (19.6%) | 0.55 | |

*Primagravida or breastfeeding first child = Pregnant persons reporting no children (under age 18) and lactating persons reporting one child; Multigravida = pregnant persons reporting one or more child and lactating persons reporting two or more children





Quantitative Results

Knowledge, attitudes, and beliefs of sample, stratified by number of children:

 There were no differences between primagravida or breastfeeding a first child and multigravida or breastfeeding a subsequent child related to self-efficacy perceived barriers, safety, and vaccine effectiveness.

| Construct (no. of items) | Level | Total (n=400) | Primagravida or breastfeeding first child (n=140, 35.2%) | Multigravada or breastfeeding subsequent child (n=260, 64.8%) | p- value | |
|--|--|-------------------------|---|---|-------------|--|
| Self-efficacy | High self-efficacy | 346 (86.5% | 121 (86.4%) | 225 (86.5%) | 0.98 | |
| (1 item) | Low self-efficacy | 54 (13.5%) | 19 (13.6%) | 35 (13.5%) | 0.90 | |
| Perceived barriers | Low perceived barriers | 333 (83.2%) | 117 (83.6%) | 216 (83.1%) | 0.90 | |
| (1 item) | High perceived barriers | 67 (16.8%) | 23 (16.4%) | 44 (16.9%) | 0.90 | |
| Safety | High confidence in vaccine safety | 388 (97.0%) | 133 (95.0%) | 255 (98.1%) | 0.085 | |
| (2 items) | Low confidence in vaccine safety | 12 (3.0%) | 7 (5.0%) | 5 (1.9%) | 0.005 | |
| Vaccine effectiveness <i>(2 items)</i> | High trust in vaccine effectiveness | 356 (89.0%) | 125 (89.3%) | 231 (88.8%) | 0.89 | |
| | Low trust in vaccine effectiveness | 44 (11.0%) | 15 (10.7%) | 29 (11.2%) | 0.09 | |

*Primagravida or breastfeeding first child = Pregnant persons reporting no children (under age 18) and lactating persons reporting one child; Multigravida = pregnant persons reporting one or more child and lactating persons reporting two or more children







DAY ONE

Quantitative Results Univariable Regression

Factors associated with higher vaccine hesitancy:

 Younger age, primagravida or breastfeeding first child, having fewer children, higher education status, and not having been vaccinated during a previous pregnancy were associated with higher vaccine hesitancy.

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|---|---|
|---|---|

| Factor | OR | p-value | 95% CI |
|--|------|---------|---------------|
| Age | | | |
| 18-29 | Ref | | |
| 30-44 | 0.46 | 0.02 | (0.24-0.88) |
| Pregnant | | | |
| Lactating / not pregnant | Ref | | |
| Pregnant | 1.52 | 0.15 | (0.85, 2.71) |
| Gestational age^ | | | |
| Second trimester (13-26 weeks) | Ref | | |
| Third trimester (from 27 weeks) | 2.38 | 0.104 | (0.84, 6.75) |
| First/subsequent children | | | |
| Multigravida | Ref | | |
| Primagravida | 3.21 | <0.001 | (1.86, 5.55) |
| Number of children under 18 years of age | | | |
| None | Ref | | |
| One | 0.59 | 0.18 | (0.27-1.28) |
| Two | 0.30 | 0.005 | (0.13-0.69) |
| Three | 0.06 | 0.001 | (0.01-0.31) |
| Four or more | 0.22 | 0.01 | (0.06-0.74) |
| Education level (highest level attained) | | | |
| Less than primary school | Ref | | |
| Primary school | 4.87 | 0.04 | (1.10, 21.50) |
| Secondary/high school | 4.26 | 0.06 | (0.95, 19.02) |
| College/university or higher | 4.81 | 0.04 | (1.07, 21.60) |
| Previous vaccination during pregnancy | | | |
| No | Ref | | |
| Yes | 0.29 | 0.04 | (0.09, 0.93) |

^ Pregnant individuals in the first trimester (<13 weeks) were excluded from this study





Quantitative Results Univariable Regression

Factors associated with higher vaccine hesitancy:

 Lower supportive norms and lower self-efficacy were associated with higher vaccine hesitancy.

| Factor | OR | p-value | 95% CI |
|---------------------------------------|------|---------|--------------|
| Perceived prevalence | | | |
| Higher perceived RSV prevalence | Ref | | |
| Lower perceived RSV prevalence | 1.58 | 0.20 | (0.78, 3.20) |
| Perceived risk | | | |
| Higher perceived RSV risk | Ref | | |
| Moderate perceived RSV risk | 1.02 | 0.95 | (0.58, 1.79) |
| Lower perceived RSV risk | 1.27 | 0.63 | (0.48, 3.33) |
| Social norms | | | |
| Higher supportive norms | Ref | | |
| Lower supportive norms | 2.56 | 0.002 | (1.43, 4.58) |
| Self-efficacy | | | |
| Higher self-efficacy | Ref | | |
| Lower self-efficacy | 2.28 | 0.02 | (1.17, 4.44) |
| Perceived barriers | | | |
| Lower perceived barriers | Ref | | |
| Higher perceived barriers | 1.01 | 0.97 | (0.50, 2.06) |
| Safety | | | |
| Higher confidence in vaccine safety | Ref | | |
| Lower confidence in vaccine safety | 1.75 | 0.41 | (0.46, 6.66) |
| Vaccine effectiveness | | | |
| Higher trust in vaccine effectiveness | Ref | | |
| Low trust in vaccine effectiveness | 1.38 | 0.43 | (0.63, 3.02) |

^ Pregnant individuals in the first trimester (<13 weeks) were excluded from this study







Quantitative Results Heatmap of Concerns

When a new vaccine is approved for use and recommended for me/my family, I am typically concerned with:

Ingredients in the vaccine

Side effects of the vaccine

Availability of the vaccine at my health facility

Cost to get the vaccine

What others are saying about the vaccine

Provider recommendation to get the vaccine Family member input about me getting the vaccine

Ranking from most (1) to least concerning (7)

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|-----|----|----|----|-----|-----|-----|
| 57 | 95 | 78 | 63 | 49 | 30 | 29 |
| 205 | 75 | 40 | 38 | 20 | 12 | 11 |
| 41 | 68 | 98 | 80 | 46 | 38 | 30 |
| 27 | 66 | 62 | 76 | 55 | 39 | 76 |
| 7 | 17 | 35 | 51 | 57 | 96 | 138 |
| 38 | 57 | 56 | 51 | 103 | 61 | 35 |
| 26 | 23 | 32 | 42 | 71 | 125 | 82 |







| DAY ONE | DAY TWO | DAY THREE | DAY FOUR |
|---------|---------|-----------|----------|
| | | | |

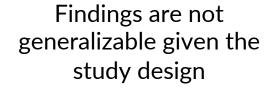


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Findings were heavily dependent on nature of cross-sectional design: when data collection occurred (ex: policy status awareness and implementation; COVID transmission in chosen participants' communities)



Social desirability bias may have impacted interviews





Data Analysis Team: Acknowledgements

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Results from Demand Generation: Discussion

We'd like to hear your feedback on the findings we just presented.

A few questions to get us started:

- Were the key questions for new vaccines (RSV, GBS) surprising to you? What kind of information would decision-makers need to feel confident about a new vaccine recommended in pregnancy?
- Our findings identify key decision-making influences. Were any of these surprising? Are there other influences that influence the decision-making process?









Wrap-Up and Key Takeaways: Day 1







